EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,627 + 90/008780 + 90/008797	07/13/2005	4739762	52734-036A	9591

32116 7590 05/07/2008

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 05/07/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

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[redacted]

THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

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McDERMOTT WILL & EMERY LLP
600 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20005-3096

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008780 + 90/008797 + 90/007627
PATENT NO. 4,739,762
ART UNI 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008797 + 90/007627 + 90/008780
PATENT NO. 4,739,762
ART UNI 3992

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,627; 90/008,780, 90/008,747	Patent Under Reexamination 4739762
	Examiner BEVERLY M. FLANAGAN	Art Unit 3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☐ Responsive to the communication(s) filed on _____ . b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-12,14-23,25-44,51 and 54* are subject to reexamination.
1b. ☒ Claims *13,24,45-50,52,53 and 55-59* are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-12, 14-23, 25-44, 51 and 54* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Extensions of time under 37 C.F.R. 1.136(a) will not be permitted in these proceedings because the provisions of 37 C.F.R. 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. § 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 C.F.R. 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 C.F.R. 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 4,739,762 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability of similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j); must

be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requested must be served on the other party (or parties where two or more third party requested proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-23, 25-44, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1980 Monograph.

The examiner finds the 1980 Monograph to be a printed publication pursuant to 35 U.S.C. § 102(b). Requester has provided considerable evidence that the 1980 Monograph was both publicly accessible and widely disseminated prior to the critical date of November 7, 1984. Dr. Palmaz provided a declaration under 37 C.F.R. 1.131 in a previous reexamination of U.S. Patent No. 4,739,762 that establishes that the 1980 Monograph was provided to several companies during the course of obtaining research

funds for the invention.[1] Various excerpts from trial testimony and depositions in litigation involving U.S. Patent No. 4,739,762, all supplied as Exhibits to the instant reexamination request, further chronicle Dr. Palmaz's interactions with the several companies.[2] It is also noted that confidentiality agreements were not executed with any of the companies contacted.[3] The examiner concludes that the evidence presented in the request demonstrates that the 1980 Monograph was disseminated and publicly available more than one year prior to the critical date of November 7, 1984 and thus, qualifies as a prior art printed publication under 35 U.S.C. § 102(b).

The 1980 Monograph teaches an expandable intraluminal graft which has a thin wall surface that is smooth prior to expansion (see Figs. 1 and 3 and page 367 of the 1980 Monograph). The 1980 Monograph teaches an intraluminal tubular structure that is capable of expansion (see page 367 and Fig. 3 of the 1980 Monograph) and described a slotted tube stent with first and second ends (see Fig. 3 of the 1980 Monograph). Fig. 3 shows a thin thickness that is smooth in a first diameter and the slots, which form peaks and valleys, are formed therein are aligned along the longitudinal axis of the stent (see also Fig. 1 of the 1980 Monograph). The 1980 Monograph teaches a stent that has a first diameter on a balloon and is delivered intraluminally through a body passageway to treat a stenosis (see Figs. 1, 3 and 4 and pages 248,351 and 366-367 of the 1980 Monograph). The 1980 Monograph teaches an expandable tubular structure having a shape memory to avoid recoil and it delivered

---

[1] The declaration was provided in Reexamination Control No. 90/002,493 and has been submitted as Exhibit M in the instant reexamination request.
[2] See, e.g., Exhibits I-R of the instant reexamination request.
[3] See the instant reexamination request, at page 7, line 20.

by a balloon catheter, whose inflation can be variably controlled (see Fig. 3 and pages 265, 266 and 267 of the 1980 Monograph).

Claims 1-12, 14-23, 25-44, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1983 Monograph.

The examiner finds the 1983 Monograph to be a printed publication pursuant to 35 U.S.C. § 102(b). Requester has provided considerable evidence that the 1983 Monograph was both publicly accessible and widely disseminated prior to the critical date of November 7, 1984. Dr. Palmaz provided a declaration under 37 C.F.R. 1.131 in a previous reexamination of U.S. Patent No. 4,739,762 that establishes that the 1983 Monograph was provided to several companies during the course of obtaining research funds for the invention.[4] Various excerpts from trial testimony and depositions in litigation involving U.S. Patent No. 4,739,762, all supplied as Exhibits to the instant reexamination request, further chronicle Dr. Palmaz's interactions with the several companies.[5] It is also noted that confidentiality agreements were not executed with any of the companies contacted.[6] The examiner concludes that the evidence presented in the request demonstrates that the 1983 Monograph was disseminated and publicly available more than one year prior to the critical date of November 7, 1984 and thus, qualifies as a prior art printed publication under 35 U.S.C. § 102(b).

---

[4] The declaration was provided in Reexamination Control No. 90/002,493 and has been submitted as Exhibit M in the instant reexamination request.
[5] See, e.g., Exhibits I-R of the instant reexamination request.
[6] See the instant reexamination request, at page 7, line 20.

The 1983 Monograph teaches an expandable intraluminal graft which has a thin wall surface that is smooth prior to expansion (see page 350 of the 1983 Monograph). The 1983 Monograph teaches an intraluminal tubular structure that is capable of expansion and described a slotted tube stent with first and second ends (see pages 349-350 of the 1983 Monograph). A thin thickness that is smooth in a first diameter and the slots, which form peaks and valleys, are formed therein are substantially parallel with and aligned along the longitudinal axis of the stent (see pages 349-350 of the 1983 Monograph). The 1983 Monograph teaches a stent that has a first diameter on a balloon and is delivered intraluminally through a body passageway to treat a stenosis (see Figs. 1, 3 and 4 and pages 248,351 and 366-367 of the 1980 Monograph). The 1983 Monograph teaches a tubular member having a second, expanded and deformed diameter upon the application from the interior of the tubular member of radially, outwardly extending force, by inflating the balloon portion of the catheter, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the passageway (see page 350 of the 1983 Monograph). The 1983 Monograph teaches an expandable tubular structure having a shape memory to avoid recoil and it delivered by a balloon catheter, whose inflation can be variably controlled (see pages 348-49 of the 1983 Monograph).

Scope of Reexamination

Since requester did not request reexamination of claims 13, 24, 45-50, 52, 53 and 55-59 and did not assert the existence of a substantial new question of patentability (SNQP) for such claims (see 35 U.S.C. § 311(b)(2); see also 37 CFR 1.915b and 1.923), such claims will not be reexamined. This matter was squarely addressed in *Sony Computer Entertainment America Inc., et al. v. Jon W. Dudas*, Civil Action No. 1:05CV1447 (E.D.Va. May 22, 2006), Slip Copy, 2006 WL 1472462. (Not Reported in F.Supp.2d.) The District Court upheld the Office's discretion to not reexamine claims in an *inter partes* reexamination proceeding other than those claims for which reexamination had specifically been requested. The Court stated:

> To be sure, a party may seek, and the PTO may grant, *inter partes* review of each and every claim of a patent. Moreover, while the PTO in its discretion may review claims for which *inter partes* review was not requested, nothing in the statute compels it to do so. To ensure that the PTO considers a claim for *inter partes* review, § 311(b)(2) requires that the party seeking reexamination demonstrate why the PTO should reexamine each and every claim for which it seeks review. Here, it is undisputed that Sony did not seek review of every claim under the '213 and '333 patents. Accordingly, Sony cannot now claim that the PTO wrongly failed to reexamine claims for which Sony never requested review, and its argument that AIPA compels a contrary result is unpersuasive.

(Slip copy at page 9.)

The *Sony* decision's reasoning and statutory interpretation apply analogously to *ex parte* reexamination, as the same relevant statutory language applies to both *inter partes* and *ex parte* reexamination. 35 U.S.C. § 302 provides that the *ex parte* reexamination "request must set forth the pertinency and manner of applying cited prior

art to every claim for which reexamination is requested" (emphasis added), and 35 U.S.C. § 303 provides that "the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request..." (Emphasis added). These provisions are analogous to the language of 35 U.S.C. § 311(b)(2) and 35 U.S.C. § 312 applied and construed in *Sony*, and would be construed in the same manner. As the Director can decline to reexamine non-requested claims in an *inter partes* reexamination proceeding, the Director can likewise do so in *ex parte* reexamination proceeding. See *Notice of Clarification of Office Policy To Exercise Discretion in Reexamining Fewer Than All the Patent Claims* (signed Oct. 5, 2006) 1311 OG 197 (Oct. 31, 2006). See also MPEP § 2240, Rev. 5, Aug. 2006.

Therefore, claims 13, 24, 45-50, 52, 53 and 55-59 were not be reexamined in this *ex parte* reexamination proceeding.

NOTICE RE PATENT OWNER'S CORRESPONDENCE ADDRESS

Effective May 16, 2007, 37 CFR 1.33(c) has been revised to provide that:

The patent owner's correspondence address for all communications in an *ex parte* reexamination or an *inter partes* reexamination is designated as the correspondence address of the patent.

> *Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination*, 72 FR 18892 (April 16, 2007)(Final Rule)

The correspondence address for any pending reexamination proceeding not having the same correspondence address as that of the patent is, by way of this revision to 37 CFR 1.33(c), automatically changed to that of the patent file as of the effective date.

This change is effective for any reexamination proceeding which is pending before the Office as of May 16, 2007, including the present reexamination proceeding, and to any reexamination proceeding which is filed after that date.

Parties are to take this change into account when filing papers, and direct communications accordingly.

In the event the patent owner's correspondence address listed in the papers (record) for the present proceeding is different from the correspondence address of the patent, it is strongly encouraged that the patent owner affirmatively file a Notification of Change of Correspondence Address in the reexamination proceeding and/or the patent (depending on which address patent owner desires), to conform the address of the proceeding with that of the patent and to clarify the record as to which address should be used for correspondence.

Telephone Numbers for reexamination inquiries:

Reexamination and Amendment Practice	(571) 272-7703
Central Reexam Unit (CRU)	(571) 272-7705
Reexamination Facsimile Transmission No.	(571) 273-9900

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JMC/

Conferee _____

EXHIBIT 2

2-COMMON OUTGOING (EX PARTES)

☐ 1449 _____
Reviewed List of Refs Cited by Appl

☐ 892. _____
List of Refs Cited by Examiner

☐ EXIN. _____
Examiner Interview Summary

☐ ~~NIRC.~~ RXNIRC _____
Notice of Intent to Issue Reexam Certificate

☐ RXADV. _____
Reexam proceeding Advisory Action

☐ RXCERT _____
Reexam Certificate

☐ RXDOR _____
Director Initiated Order for Reexam

☐ RXEPQ. _____
Reexam Exparte Quayle Action

☐ RXFR. _____
Reexam Final Rejection

☐ RXLET. _____
Reexam Misc Incoming Letter

☐ RXLITSR _____
Reexam Litigation Search

☐ RXMISC _____
Reexam Miscellaneous Outgoing Action or Letter

☐ RXRJNF _____
Reexam Non-Final Office Action

☐ RXREXO _____
Order Granting Reexamination

☐ SRFW _____
Examiner's Search Notes

OTHER

☑ RxPTGR _____
Other document (Please indicate doc code & page count)

Document Date: - - 08

08/12/04

Version 2.1

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

Kenneth L. Cage
McDermott, Will & Emery
600 13th street, N.W.
Washington, DC 20005

Date:

MAILED

MAY 15 2008

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90008949
PATENT NO. : 5195984
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/008,949	12/06/2007	5195984 C1	52734-036-D	2977

7590 05/15/2008

EXAMINER	
ART UNIT	PAPER NUMBER

BEN D. TOBOR
11757 KATY FREEWAY, SUITE 1400
HOUSTON, TX 77079

DATE MAILED: 05/15/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

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(For Patent Owner)

McDermott Will & Emery LLP
Patterson Thuente Skarr & Christensen PA
600 13th Street, NW
Washington, DC 20005-3096

(For Third Party Requester)

MAILED

MAY 15 2008

CENTRAL REEXAMINATION UNIT

In re Cordis Corporation :
Ex Parte Reexamination Proceeding : DECISION
Control No.: 90/008,949 : GRANTING
Filed: December 6, 2007 : PETITION
For: U.S. Patent No. 5,195,984 C1 :

The 90/008949 *ex parte* reexamination proceeding is before the Office of Patent Legal Administration for consideration of the third party requester's February 19, 2008 petition entitled "Petition Seeking Suspension of the Rules Under the Provisions Of 37 C.F.R. 1.183 to Enter a Supplemental Petition Regarding Recent Federal Circuit Authority .... "

The petition is granted to the extent set forth below.

PETITION FEE

The petition fee of $400.00 set by 37 CFR 1.17(f), as required by 37 CFR 1.183, is being charged to Deposit Account No. 50-0417.

REVIEW OF FACTS

1. U.S. Patent No. 5,195,984 (the '984 patent) issued to Richard A. Schatz on March 23, 1993, and is currently assigned to Cordis Corporation.

2. A first request for *ex parte* reexamination of the '984 patent was filed by a third party requester on July 13, 2005 and was assigned Control Number 90/007,628 ("the '628 reexamination proceeding"). Reexamination was requested for "at least claims 1 and 3" of the '984 patent.

3. On October 11, 2005, *ex parte* reexamination was ordered for claims 1-6 (*i.e.*, all of the claims) of the '984 patent.

4. On April 26, 2006, the first Office action on the patentability of the claims of the '984 patent was mailed. The Office action was a "*Notice of Intent to Issue Ex Parte Reexamination Certificate*," and it stated that the patentability of all of the claims of the '984 patent "are confirmed."

5. On October 3, 2006, an "EX PARTE REEXAMINATION CERTIFICATE" for U.S. Patent No. 5,195,984 was published, confirming the patentability of all of the patent claims, without amendment.

6. On December 6, 2007, a second request for *ex parte* reexamination of the '984 patent was filed by the same third party requester and was assigned Control Number 90/008,949 (the '949 reexamination proceeding). Reexamination was requested for "at least claims 1 and 3" of the '984 patent.

7. On January 18, 2008, the request for *ex parte* reexamination in the '949 reexamination proceeding was denied by the Primary Examiner.

8. On February 19, 2008, third party requester filed a petition under 37 CFR 1.515(c), for supervisory review and reconsideration of the Primary Examiner's January 18, 2008 Order denying reexamination in the '949 *ex parte* reexamination proceeding.

9. On April 10, 2008, patent owner filed the present petition under 37 CFR 1.183 to suspend the rules in order to permit the entry and consideration of a concurrently filed supplemental 37 CFR 1.515(c) petition for the purpose of bringing a recent decision of the Court of Appeals for the Federal Circuit and a recent decision of the USPTO Board of Patent Appeals and Interferences ("BPAI") to the attention of the deciding Official who will address the February 19, 2008 petition.

DISCUSSION

I. Background

On July 13, 2005 the '628 request for *ex parte* reexamination of the claims of the '984 patent was filed by a third party requester. Reexamination was ordered in the '628 *ex parte* reexamination proceeding. On October 3, 2006, an *ex parte* reexamination certificate for the '984 patent issued based on the '628 reexamination proceeding, in which all of the '984 patent claims were confirmed as being patentable.

The present '949 *ex parte* reexamination proceeding for the '984 patent resulted from a request filed on December 6, 2007, by a third party requester. The '949 request for reexamination alleged that certain prior patents and printed publications established a substantial new question of patentability (SNQ) for certain of the '984 patent claims. The prior patents and printed publications relied upon to establish an SNQ in the '949 request for reexamination were determined by the examiner to be the same prior patents and printed publications that had been relied upon to establish an SNQ for the '984 patent claims in the earlier filed '628 *ex parte* reexamination proceeding.

Office practice, as set forth at MPEP §2242 is that:

> "[A] "substantial new question of patentability" is not raised by prior art presented in a reexamination request if the Office has previously considered (in an earlier examination of the patent) the same question of patentability as to a patent claim favorable to the patent owner based on the same prior art patents or printed publications. *In re Recreative Technologies*, 83 F.3d 1394, 38 USPQ2d 1776 (Fed. Cir. 1996).

On January 18, 2008, the Primary Examiner denied the request for reexamination in the '949 reexamination proceeding on the basis that the request did not demonstrate any SNQ for the '984 patent claims, because (1) the request was based only on prior patents and printed publications that had established the SNQ for the '984 patent claims in the earlier '628 *ex parte* reexamination proceeding (i.e., "old art"), and (2) no "new light" has been shed by the request on the cited "old art" references. On February 19, 2008, third party requester (hereinafter "petitioner") in the '949 reexamination proceeding filed a petition, as permitted by 37 CFR 1.515(c), and as discussed in MPEP §2248, requesting supervisory review and reconsideration of the Primary Examiner's Order dated January 18, 2008 denying *ex parte* reexamination. Petitioner's asserted basis for requesting supervisory review and reconsideration of the Primary Examiner's Order may be summarized as follows:

> (1) The law regarding the manner in which 35 U.S.C. § 103 nonobviousness is to be determined has recently been "changed" by the United States Supreme Court in *KSR Int'l Co. V. Teleflex Inc.*, ., 550 U.S. _; 127 S. Ct. 1727; 82 USPQ2d 1385 (2007) ("*KSR*");
>
> (2) Due to that "change," the request for reexamination filed in the '949 *ex parte* reexamination proceeding raises an SNQ for the '984 patent claims, because it presents the prior patents and printed publications previously considered to raise an SNQ in the '628 *ex parte* reexamination (but that were not considered to render any patent claims unpatentable for "obviousness" under 35 U.S.C § 103), and *KSR* necessarily presents the same prior art "in a new light" in the '949 *ex parte* reexamination proceeding; and
>
> (3) Reexamination should, therefore, be ordered in the '949 *ex parte* reexamination proceeding in accordance with the practice discussed at MPEP § 2242(II)(A).

II. Relief Requested

The present petition requests waiver of the regulations pursuant to 37 CFR 1.183 in order to permit entry and consideration of a concurrently filed supplemental 37 CFR 1.515(c) petition presenting additional authority from the Court of Appeals for the Federal Circuit and the USPTO Board of Patent Appeals and Interferences on the manner in which the *KSR* decision has been applied by these tribunals.

III. Decision

After briefly reviewing the petition filed on February 19, 2008, and the authorities provided in the present third party requester petitions, and in light of the unique facts and circumstances of this proceeding, which present a matter of first impression, it appears that it is in the interest of justice to address all currently available input in this matter of first impression. Accordingly, the petition is granted.

CONCLUSION

1. The third party requester petition filed on April 10, 2008 is granted.

2. Jurisdiction over the '949 *ex parte* reexamination proceeding is returned to the Central Reexamination Unit to address the February 19, 2008 petition under 37 CFR 1.515(c) and the present supplemental 37 CFR 1.515(c) petition.

3. Telephone inquiries related to the present decision should be directed to Stephen Marcus, Senior Legal Advisor, at 571-272-7743, or, in his absence, to the undersigned, at 571-272-7710.

Kenneth M. Schor
Senior Legal Advisor
Office of Patent Legal Administration

sm
May 13, 2008

May 13, 2008
C:\kiva\kenpet 7\Deny_reex\8949 grant 1.183 - to enter suppl 515 re new Fed Cir KSR-type decision.doc

EXHIBIT 3

United States Patent [19]

Palmaz

[11] **Patent Number: 4,739,762**

[45] **Date of Patent: Apr. 26, 1988**

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

[75] Inventor: **Julio C. Palmaz,** San Antonio, Tex.

[73] Assignee: **Expandable Grafts Partnership,** San Antonio, Tex.

[21] Appl. No.: **923,798**

[22] Filed: **Nov. 3, 1986**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 796,009, Nov. 7, 1985.

[51] **Int. Cl.**[4] **A61M 29/00**

[52] **U.S. Cl.** **128/343;** 604/104; 604/96; 623/1

[58] **Field of Search** ..... 604/93, 49, 343, 97; 623/2; 128/344, 343, 1 R

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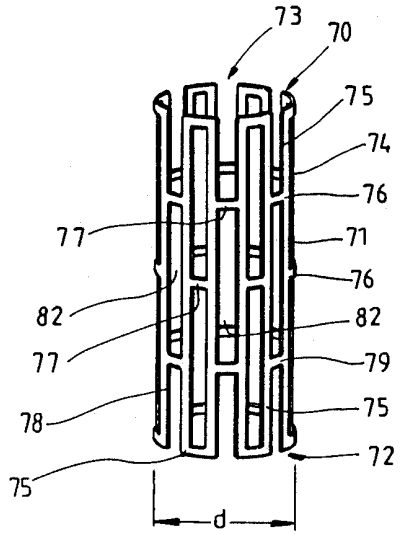
[57] **ABSTRACT**

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.

43 Claims, 2 Drawing Sheets



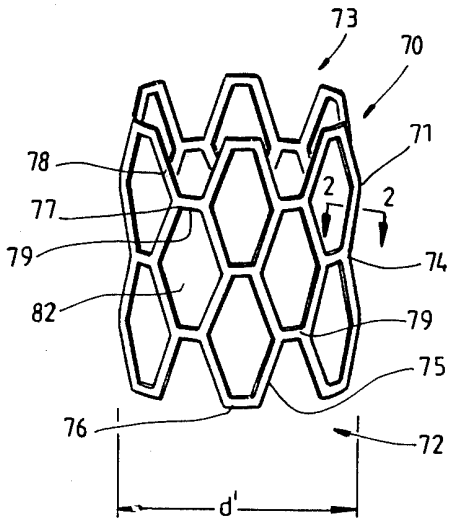


Fig. 2

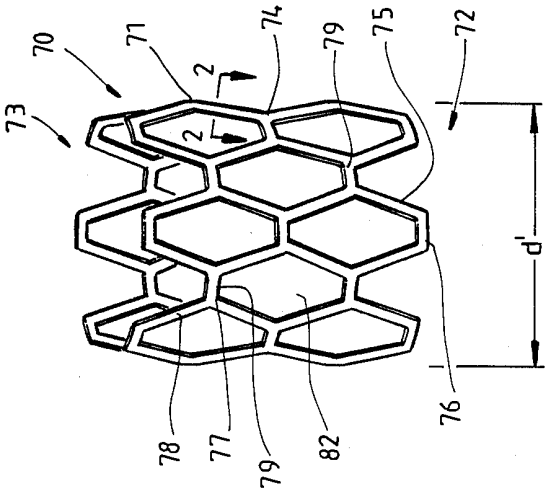


Fig. 1B

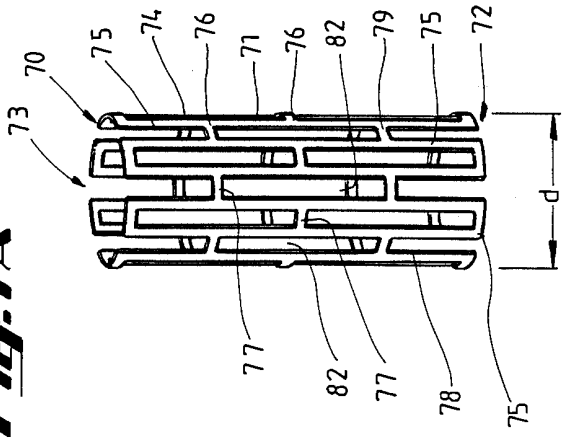
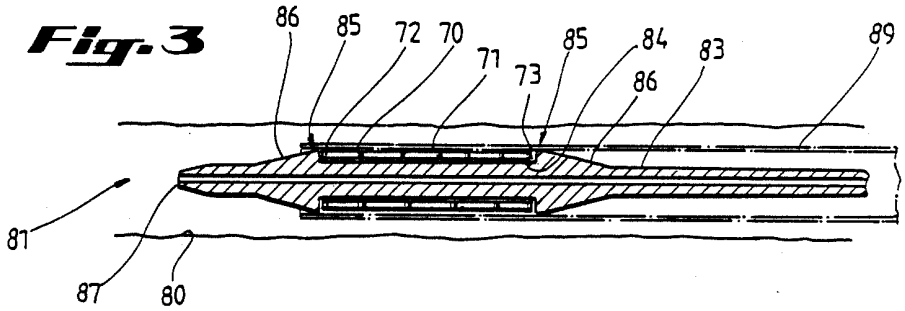


Fig. 1A

Fig. 3



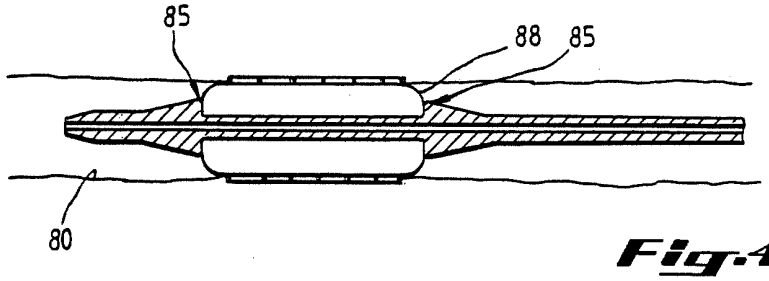
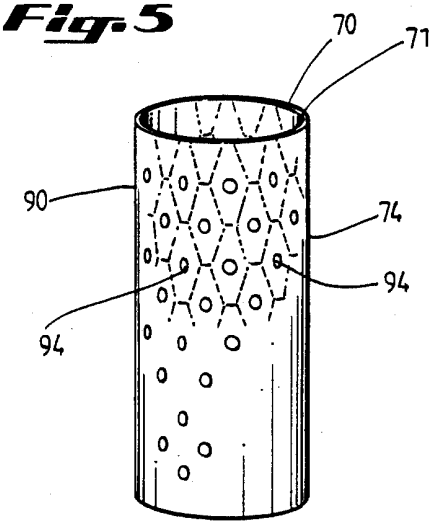


Fig. 4

Fig. 5



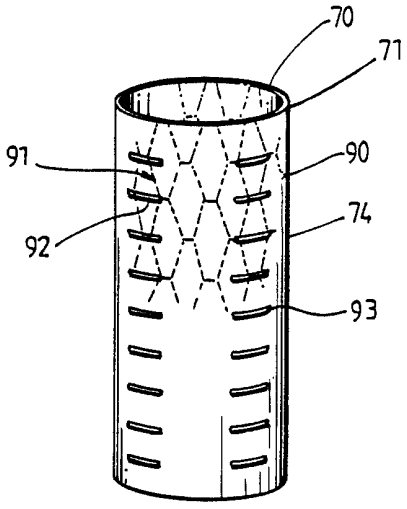


Fig. 6

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part of Applicant's co-pending application Ser. No. 06/796,009 filed Nov. 7, 1985 entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermined the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surfact of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catherization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angoiplasties of graft-artery anastomotic strictures and postendar-

terectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen; and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member. An additional feature of the present invention is that the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter. A further feature of the present invention is that the tubular shaped member may have a biological inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a prosthesis within a body passageway. The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; disposing the prosthesis upon a catheter; inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

A further feature of the present invention is that the portion of the catheter in contact with the prosthesis may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable and deformable, thin-walled tubular prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prosthesis.

The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of

stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1A** is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. **1B** is a perspective view of the graft, or prosthesis, of FIG. **1A**, in its expanded configuration when disposed within a body passageway;

FIG. **2** is a cross-sectional view of the prosthesis taken along line **2–2** of FIG. **1B**;

FIG. **3** is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. **1A**;

FIG. **4** is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. **1B**; and

FIGS. **5** and **6** are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. **1A** and **1B**, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, **70** is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses **70** may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of cathether created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" emcompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" emcompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. **1A** and **1B**, the expandable intraluminal vascular graft, or prosthesis, **70** is shown to generally comprise a tubular member **71** having first and second ends **72**, **73** and a wall surface **74** disposed between the first and second ends **72**, **73**. Tubular member **71** has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member **71** into a body passageway **80** having a lumen **81** (FIG. **3**). With reference to FIG. **1B**, upon the application from the interior of the tubular member **71** of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member **71** has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to deform the tubular member **71**.

Tubular member **71**, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, **70** may come into contact. Tubular member **71** must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member **71** to be expanded and deformed from the configuration shown in FIG. **1A** to the configuration shown illustrated in FIG. **1B** and further to permit the tubular member **71** to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. **1B** and resist radial collapse. Suitable materials for the fabrication of tubular member **71** would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member **71** is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots **82** are formed in the wall surface **74** of tubular member **71**. As seen in FIG. **1A** when tubular member **71** has the first diameter d, the slots **82** are disposed substantially parallel to the longitudinal axis of the tubular member **71**. As seen in FIG. **1A**, the slots **82** are preferably uniformly and circumferentially spaced from adjacent slots **82**, as by connecting members **77**, which connecting members **77** preferably have a length equal to the width of slots **82**, as seen in FIG. **1A**. Slots **82** are further uniformly spaced from adjacent slots **82** along the longitudinal axis of the tubular member **71**, which spacing is preferably equal to the width of connecting members **77**. Thus, the formation of slots **82** results in at least one elongate member **75** being formed between adjacent slots **82**, elongate member **75** extending between the first and second ends, **72**, **73** of tubular member **71**, as seen in FIG. **1A**.

Still with reference to FIG. **1A**, each slot will have first and second ends with a connecting member **77** disposed at the first and second ends of slots **82**. Preferably, the first and second ends of each slot **82** are disposed intermediate the first and second ends of adjacent slots **82** along the longitudinal axis of the tubular member **71**. Thus, connecting members **77**, which are disposed at the first and second ends of each slot **82**, and between elongate members **75**, will in turn be disposed

intermediate the first and second ends of adjacent slots **82** along the longitudinal axis of the tubular member **71**. Accordingly, slots **82** are preferably uniformly and circumferentially spaced from adjacent slots, and slots **82** adjacent to one another along the longitudinal axis of tubular member **71** are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member **71** at both the first and second ends **72, 73** of tubular member **71** will only have a length equal to approximately one-half of the length of a complete slot **82**, such half-slot **82** being bounded by members **78, 79**, at both the first and second ends **72, 73** of tubular member **71**. Although the graft, or prosthesis, **70** of FIGS. **1A** and **1B** is illustrated to have a length approximately equal to the length of two slots **82**, it should be apparent that the length of the graft **70** could be made longer or shorter as desired. Use of the term "slot" encompasses an opening whose length is substantially greater than its width, such as an elongated oval opening.

The foregoing described construction of graft, or prothesis, **70** permits graft, or prothesis, **70** to be expanded uniformly, and outwardly, into the configuration shown in FIG. **1B**, upon the application of a suitable force from the interior of tubular member **71**, as will be hereinafter described in greater detail. The expansion of tubular member **71** into the configuration shown in FIG. **1B** is further uniform along the length of tubular member **71**, not only because of the uniform spacing between slots **82**, as previously described, but also because the thickness of the wall surface **74**,.or the thickness of connecting members **77**, elongate members **75**, and members **78, 79**, is the same uniform thickness. As illustrated in FIG. **2**, the uniform thickness of elongate member **75** is shown, and the preferred cross-sectional configuration of elongate member **75**, connecting member **77**, and members **78, 79**, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prothesis, **70** could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface **74** of graft, or prothesis, **70**, which would be in contact with the body passageway **80** FIG. **4**), should be relatively smooth.

With reference to FIG. **1B**, it is seen that after the graft, or prothesis **70**, has been expanded and deformed into the configuration of FIG. **1B**, the slots **82** will assume a substantially hexagonal configuration when the tubular member **71** has the second, expanded diameter, d', as shown in FIG. **1B**. Such a hexagonal configuration will result when the slots **82** initially have a substantially rectangular configuration when the tubular member **71** has the first diameter, d, illustrated in FIG. **1A**. It should be noted that were the width of slots **82** to be substantially reduced, whereby the length of connecting member **77** would approximate a single point intersection, the expansion of such a tubular member **71** would result in slots **82** assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member **71** expanded from the configuration shown in FIG. **1A** to achieve the configuration shown in FIG. **1B**, but tubular member **71** is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, **70** is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member **71**. Accordingly, the force is sufficient to permanently bend elongate members **75** whereby segments of the elongate members **75** pivot about connecting members **77** and move in a circumferential direction as they pivot, whereby the diameter of the tubular member **71** increases from the first diameter, d, to the expanded diameter, d', of FIG. **1B**. The force to be applied to expand tubular member **71**, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member **71**, but also to deform elongate member **75**, in the manner previously described, whereby the portions of the elongate members **75** which pivot about the ends of connecting members **77** do not "spring back" and assume their configuration shown in FIG. **1A**, but rather retain the configuration thereof in FIG. **1B**. Once graft, or prothesis, **70** has been expanded and deformed into the configuration shown in FIG. **1B**, graft, or prothesis **70**, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member **71** has the first diameter, d, shown in FIG. **1A**, or after tubular member **71** has been expanded and deformed into the second, expanded diameter, d', of FIG. **1B**, tubular member **71** does not exert any outward, radial force, in that tubular member **71** is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. **3** and **4**, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. **3** and **4**, an expandable intraluminal vascular graft, or prosthesis, **70**, of the type described in connection with FIGS. **1A** and **1B**, is disposed or mounted upon a catheter **83**. Catheter **83** has an expandable, inflatable portion **84** associated therewith. Catheter **83** includes means for mounting and retaining **85** the expandable intraluminal vascular graft, of prosthesis, **70** on the expandable, inflatable portion **84** of catheter **83**. Preferably, the mounting and retaining means **85** comprises retainer ring members **86** disposed on the catheter **83** adjacent the expandable inflatable portion **84** of catheter **83**; and a retainer ring member **86** is disposed adjacent each end **72, 73** of the expandable intraluminal vascular graft, or prosthesis, **70**. Preferably, as seen in FIG. **3**, retainer ring members are formed integral with catheter **83**, and the retainer ring member **86** adjacent the leading tip **87** of catheter **83** slopes upwardly and away from catheter tip **87** in order to protect and retain graft or prosthesis, **70** as it is inserted into the lumen **81** of body passageway **80**, as to be hereinafter described in greater detail. The remaining retainer ring member **86** as shown in FIG. **3**, slopes downwardly away from tip **87** of catheter **83**, to insure easy removal of catheter **83** from body passageway **80**. After expandable intraluminal graft, or prosthesis, **70** has been disposed upon catheter **83**, in the manner previously described, the graft, or prosthesis, **70** and catheter **83** are inserted within a body passageway **80** by catheterization of the body passageway **80** in a conventional manner.

In a conventional manner, the catheter **83** and graft, or prosthesis, **70** are delivered to the desired location within the body passageway **80**, whereat it is desired to expand the lumen **81** of body passageway **80** via intraluminal graft **70**, or where it is desired to implant prosthesis **70**. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter **83** and graft, or prosthesis, **70** are delivered to the desired location within the body passageway. Prosthesis, or graft, **70** is then expanded and deformed by expanding the expandable, inflatable portion **84** of catheter **83**, whereby the prosthesis, or graft, **70** is expanded and deformed radially, outwardly into contact with the body passageway **80**, as shown in FIG. **4**. In this regard, the expandable, inflatable portion of catheter **83** may be a conventional angioplasty balloon **88**. After the desired expansion and deformation of prosthesis, or graft, **70** has been accomplished, angioplasty balloon **88** may be collapsed, or deflated, and the catheter **83** may be removed in a conventional manner from body passageway **80**. If desired, as seen in FIG. **3**, catheter **83**, having graft or prosthesis, **70** disposed thereon, may be initially encased in a conventional Teflon TM sheath **89**, which is pulled away from prosthesis, or graft, **70**, prior to expansion of the prosthesis, or graft, **70**.

Still with reference to FIGS. **3** and **4**, it should be noted that tubular member **71** of prosthesis, or graft, **70** initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. **1A**, in order to permit the insertion of the tubular member, **71** into the body passageway **80** as previously described. When it is desired to implant prosthesis **70** within a body passageway **80** for the purposes previously described, the prosthesis **70** is expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway **80**, as shown in FIG. **4**. Accordingly, the expanded and deformed prosthesis **70**, upon deflation of angioplasty balloon **88** will not be able to migrate from the desired location within the body passageway **80**, nor will the expansion of the prosthesis **70** be likely to cause a rupture of the body passageway **80**. Furthermore, insofar as prosthesis, or graft, **70** is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway **80** in excess of that required to resist radial collapse of the body passageway **80**. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft **70** to expand the lumen **81** of a body passageway **80** having an area of stenosis, the expansion of intraluminal vascular graft **70** by angioplasty balloon **88**, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft **70**, whereby vascular graft **70** prevents the body passageway **80** from collapsing and decreasing the size of the previously expanded lumen **81**. Once again, the second, expanded diameter d' of intraluminal vascular graft **70**, as shown in FIG. **4**, is variable and determined by the desired expanded internal diameter of body passageway **80**. Thus, the expandable intraluminal graft **70** will not migrate away from the desired location within the body passageway **80** upon deflation of angioplasty balloon **88**, nor will the expansion of intraluminal graft **70** likely cause a rupture of body passageway **80**, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway **80** at the location of graft **70**, graft **70** will insure that such an intimal flap will not be able to fold inwardly into body passageway **80**, nor tear loose and flow through body passageway **80**. In the situation of utilizing graft **70** in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon **88** one time in order to expand and deform graft **70**, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft **70**, potentially 80% of the endothelium is exposed through the openings or expanded slots **82** of graft **70**. It is further believed that intact patches of endothelium within expanded slots **82** of graft **70** may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. **5** and **6**, prostheses, or grafts, **70** of the type previously described in connection with FIGS. **1A** and **1B** are shown, and the tubular members **71** of grafts, or prostheses, **70** have a biologically inert coating **90** placed upon wall surfaces **74** of tubular shaped members **71**. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating **90** should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, **70**. Coating **90** may be further provided with a means for anchoring **91** (FIG. **6**) the tubular member **71** to the body passageway **80**. Anchoring means **91** may be comprised of a plurality of radially, outwardly extending projections **92** formed on the coating **90**. As seen in FIG. **6**, the radially outwardly extending projections **92** could comprise a plurality of ridges **93**, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings **94** formed in coating **90**, as shown in FIG. **5**, whereby the fluid contained in body passageway **80** can be in direct contact with the dilated, or expanded, body passageway area.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obviously modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I claim:

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

2. The method of claim **1**, further including the steps of: collapsing the portion of the catheter associated with the prosthesis, and removing the catheter from the body passageway.

3. The method of claim **1**, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim **1**, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

5. The method of claim **4**, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

6. The method of claim **5**, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

7. The method of claim **1**, wherein the thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby the expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of the thin-walled tubular member does not cause a rupture of the body passageway.

8. The method of claim **7**, wherein the thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

9. The method of claim **1**, wherein the thin-walled tubular member is provided with a biologically inert coating on the outer surface of the thin-walled tubular member.

10. The method of claim **9**, wherein the coating is provided with a means for anchoring the prosthesis to the body passageway.

11. The method of claim **10**, wherein the means for anchoring is the coating being provided with a plurality of radially, outwardly extending projections for engagement with the body passageway.

12. The method of claim **9**, wherein the coating is provided with a plurality of openings to allow communication between the body passageway and the interior of the thin-walled tubular member.

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

14. The expandable intraluminal vascular graft of claim **13**, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

15. The expandable intraluminal vascular graft of claim **14**, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

16. The expandable intraluminal vascular graft of claim **13**, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim **13**, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim **13**, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim **13**, wherein the tubular member has a biologically inert coating on the wall surface.

20. The expandable intraluminal vascular graft of claim **19**, wherein the coating includes a means for anchoring the tubular member to the body passageway.

21. The expandable intraluminal vascular graft of claim **20**, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

22. The expandable intraluminal vascular graft of claim **19**, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

23. The expandable intraluminal vascular graft of claim **13**, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

24. An expandable prosthesis for a body passageway, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

25. The expandable prosthesis for a body passageway of claim **24**, wherein the tubular member has a biologically inert coating on the wall surface.

26. The expandable prosthesis for a body passageway of claim **25**, wherein the coating includes a means for anchoring the tubular member to the body passageway.

27. The expandable prosthesis for a body passageway of claim **26**, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

28. The expandable prosthesis for a body passageway of claim **25**, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

29. The expandable prosthesis of claim **24**, wherein the the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

30. The expandable prosthesis of claim **29**, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

31. The expandable prosthesis of claim **24**, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

32. The expandable prosthesis of claim **24**, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim **24**, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

34. The expandable prosthesis of claim **24**, wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim **35**, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable, tubular prosthesis.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

38. The apparatus of claim **37**, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable intraluminal vascular graft.

39. The method of claim **1**, wherein tantalum is utilized for the tubular member.

40. The expandable intraluminal vascular graft of claim **13**, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim **24**, wherein tantalum is utilized for the tubular member.

42. The apparatus of claim **35**, wherein tantalum is utilized for the tubular prosthesis.

43. The apparatus of claim **37**, wherein tantalum is utilized for the intraluminal vascular graft.

* * * * *

US004739762B1

REEXAMINATION CERTIFICATE (3650th)

United States Patent [19]

Palmaz

[11] B1 4,739,762

[45] Certificate Issued Oct. 27, 1998

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

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Reexamination Request:
No. 90/004,785, Oct. 6, 1997

Reexamination Certificate for:

Patent No.:	**4,739,762**
Issued:	**Apr. 26, 1988**
Appl. No.:	**923,798**
Filed:	**Nov. 3, 1986**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 796,009, Nov. 7, 1985, Pat. No. 4,733,665.

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/108**; 604/104; 604/96; 623/1

[58] **Field of Search** 606/155, 156, 606/108, 198, 191, 195; 623/1, 12

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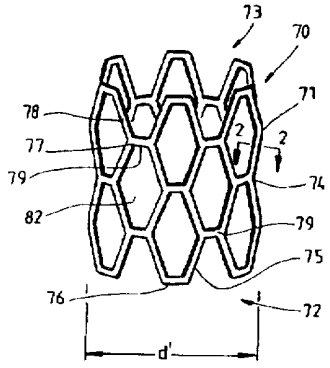
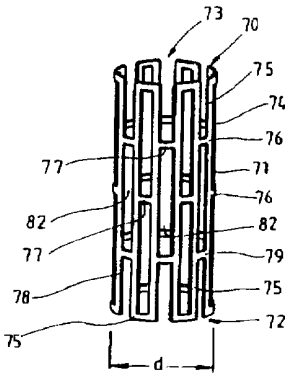
Primary Examiner—Michael H. Thaler

[57] **ABSTRACT**

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.





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REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE SPECIFICATION AFFECTED BY AMENDMENT ARE PRINTED HEREIN.

Column 7, after line 20:

With reference to FIGS. 1A and 1B, it is seen that certain of the slots 82 formed in tubular member 71 are open ended slots. The circumferentially adjacent slots 82, whether open ended or closed, define ring portions that are defined by a plurality of peak portions and valley portions. In the preferred embodiment, the ring portions at the first and second ends 72, 73 are not in phase with each other. Also in the preferred embodiment, open ended slots are defined by a pair of spaced apart elongate members 75 that are connected together by a connecting member 77 that extends between one end of each of the elongate members 75.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **23** and **34** is confirmed.

Claims **13** and **24** are cancelled.

Claims **1**, **14**, **16–19**, **25**, **29**, **31–33**, **35**, **37**, **40** and **41** are determined to be patentable as amended.

Claims **2–12**, **15**, **20–22**, **26–28**, **30**, **36**, **38**, **39**, **42** and **43**, dependent on an amended claim, are determined to be patentable.

New claims **44–59** are added and determined to be patentable.

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at [a desired] *the* location *of an existing natural obstruction* within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

14. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

16. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein the tubular member has a biologically inert coating on the wall surface.

25. The expandable prosthesis for a body passageway of claim **[24]** *34*, wherein the tubular member has a biological inert coating on the wall surface.

29. The expandable prosthesis of claim **[24]** *34*, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjcent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

31. The expandable prosthesis of claim **[24]** *34*, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second expanded diameter.

32. The expandable prosthesis of claim **[24]** *34*, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter, and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim **[24]** *34*, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed intop the second expanded diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a *substantially uniform thickness and a* plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis, *the prosthesis having a first diameter which permits intraluminal delivery of the prosthesis into a body passageway having a lumen and wherein the outside of the wall surface of the prosthesis is a smooth surface when the prosthesis has the first diameter*; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall

surface disposed between the first and second ends, the wall surface having a *substantially uniform thickness and a* plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft, *the vascular graft having a first diameter which permits intraluminal delivery of the graft into a body passageway having a lumen and wherein the outside of the wall surface of the graft is a smooth surface when the graft has the first diameter*; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

40. The expandable intraluminal vascular graft of claim **[13]** *23*, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim **[24]** *34*, wherein tantalum is utilized for the tubular member.

44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:

utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the stent prosthesis upon a catheter having an inflatable balloon portion;

inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;

delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and

expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

45. The method of claim 44 wherein at least certain of the slots are defined by a pair of spaced apart elongate members that are connected together at one end of each of the elongate members so as to define an open ended slot.

46. The method of claim 44, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

47. The method of claim 46, wherein said tubular member has a first end and a second end and includes one of said ring portions at said first and second ends thereof.

48. The method of claim 46, wherein the tubular member is formed from a plastically deformable material.

49. The method of claim 46, wherein the stent prosthesis after expansion has mechanical strength sufficient to provide radial support of the body passageway and prevent migration of the stent prosthesis within the body passageway.

50. The method of claim 46, wherein the tubular member has an outer wall surface and the slots formed in the outer wall surface upon expansion of the tubular member define open areas of approximately eighty percent (80%) of the area of the wall surface.

51. In combination, a balloon expandable stent prosthesis for implantation in the passageway of a coronary artery having an area of stenosis and a catheter, comprising:

an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer wall surface disposed between the first and second ends, the wall having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member,

a catheter having an expandable, inflatable balloon portion;

the tubular member being disposed on the balloon portion of the catheter;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter upon the application from the interior of the tubular member of radially, outwardly extending force, by inflating the balloon portion of the catheter, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

52. The combination of claim 51, wherein at least certain of the slots are defined by a pair of spaced apart elongate members that are connected together at one end of each of the elongate members so as to define an open ended slot.

53. The combination of claim 52, wherein a connecting member extends between and connects said one end of each of the elongate strut members.

54. The combination of claim 51, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

55. The combination of claim 54, wherein said tubular member includes one of said ring portions at its first and second ends.

56. The balloon expandable stent prosthesis of claim 55, wherein the ring portions at the first and second ends are not in phase with each other.

57. The combination of claim 51, wherein the tubular member is formed of a plastically deformable material.

58. The combination of claim 51, wherein the tubular member in its second, expanded diameter has mechanical strength sufficient to provide radial support of the coronary artery and prevent migration of the tubular member from the area of stenosis.

59. The combination of claim 51, wherein the slots formed in the wall surface of the tubular member in its second, expanded diameter define open areas of approximately eighty percent (80%) of the area of the wall surface.

* * * * *

EXHIBIT 4

Radiology

NOVEMBER/1984 Volume 153 (P) Special Edition

Head and Neck Radiology · Nuclear Medicine · Diagnostic Radiology · Computed Tomography · Radiation Physics · Interventional Radiology ·

70TH Scientific Assembly and Annual Meeting

Washington, D.C. November 25–30, 1984

Magnetic Resonance · Pediatric Radiology · Ultrasound · Radiation Biology · Therapeutic Radiology · Neuroradiology

including sessions in joint sponsorship with the American Association of Physicists in Medicine

SCIENTIFIC PROGRAM

Works in Progress—General Diagnosis

Thursday Afternoon —Nov. 29, 1984 **2:45-3:45 P.M.**
Computer Code: U16 Credits: 1 hour

Room 36

Barry D. Toombs, M.D., Houston, TX, Presiding

2:45 P.M.

991. Angioscopy: Application in Arterial Occulsive Disease

Amir Motarjeme, M.D., Chicago, IL, Bruno Conte, M.D.

The nature of occlusion has a great significance in management of arterial occlusive disease. Not infrequently, angiography alone is unable to differentiate between atherosclerotic and thromboembolic arterial occlusive disease. With percutaneous transluminal angioplasty being accepted as an alternate to surgery in management of atherosclerotic occlusive disease, it is essential to be able to differentiate between arterial occlusions due to atherosclerosis and thromboembolic disease. With commercially available small caliber angioscopes (4–8 F) it is now possible to look at the arterial occlusive lesions directly to arrive at a correct diagnosis. We report on our limited experience in angioscopy both prior to and after percutaneous transluminal angioplasty to evaluate the nature of occlusion and also to observe the result of PTA.

2:53 P.M.

992. Mediastinal Lymphography Using Water Soluble Contrast Medium

Taneyasu Tauchi, M.D., Nagoya City, Japan, Michio Kono, M.D., Hirochika Suzuki, M.D., Kenji Kurono, M.D., Eriko Okumura, M.D., Michimasa Matsuo, M.D.

In cases of lung cancer, the diagnosis of lymphnodal metastasis is very important, before surgery or conservative therapy is started. Some diagnostic modalities, such as CT, bronchial arteriography, and radionuclide studies, are available for this purpose; however, these studies do not always supply accurate information. Some clinical trials of mediastinal lymphography using oily contrast medium have been carried out, but practical applications of these agents have been limited. According to our preliminary data derived from canine experiments, contrast medium of low viscosity and low permeability was well adapted for mediastinal lymphography. Based on this result, we performed mediastinal lymphography in a clinical setting using metrizamide—a nonionic and water-soluble contrast medium. In 23 cases of lung cancer, mediastinal lymphography was performed at thoracotomy. Five to 10 ml of metrizamide was injected directly into mediastinal lymph nodes. The mediastinal lymphographic findings correlated well with histological findings. A trial of mediastinal lymphography with transbronchial injection of metrizamide bronchoscopically was performed, and the results will be reported.

3:01 P.M.

993. Expandable Intraluminal Graft: A Preliminary Study

Julio C. Palmaz, M.D., San Antonio, TX, Randy R. Sibbitt, M.D., Stewart R. Reuter, M.D., J.D., Fermin O. Tio, M.D., William J. Rice, M.D.

In an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire with soldered cross points. The resulting tubular mesh has a wall thickness of 20–45 microns and a 98% open surface. Eleven grafts of six, eight, and 10 ml in diameter by 20 ml in length were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies up to 8.5 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. No long-term anticoagulation was used. Light and electron microscopy studies showed complete endothelization of the inner surface of the graft at three weeks.

3:09 P.M.

994. Experimental Results with a New Vena Caval Filter

Rolf W. Günther, M.D., Mainz, West Germany, Hans Schild, M.D., S. Storkel, M.D., A. Fries

A new inferior vena cava filter device was studied in 24 dogs. The filter consists of a steel wire basket and several struts. It can be introduced percutaneously through a 10-F Teflon catheter under fluoroscopic control. The construction of the filter allows antegrade and retrograde placement and extraction in case of malposition. Due to the firm attachement of the device to the intimal surface and fibrotic encasement of the wires in the vessel wall, displacement and tilting of the filter are avoided. *In vivo* and *in vitro* studies demonstrated the capability of the filter to entrap emboli as small as 15X2 mm in 90% of cases; all larger emboli were trapped. Long-term thrombogenicity studies 3–4 months after filter insertion showed patency of the inferior vena cava in six dogs.

3:17 P.M.

995. Fibrinolytic Therapy by Means of Intrathrombotic Injections of Streptokinase: Technique and Clinical Experience in Chronic Arterial Occulsion

Johannes Lammer, M.D., Graz, Austria, Ernst Pilger, M.D., Erwin Jusitch, M.D., Klaus Neumayer, M.D., Herbert Schreyer, M.D.

Local fibrinolytic therapy of chronic arteriosclerotic obstructions by means of intraarterial infusion of streptokinase had a success rate of only 50% or less. Due to collateral vessels originating proximal to the tip of the thrombus, only minimal doses of infused streptokinase come in contact with the thrombus. Therefore, a technique was developed to infiltrate the thrombus with streptokinase from inside by means of intrathrombotic injections. The tip of the endhole catheter had to be within the thrombus during the entire procedure. Two thousand five hundred units of streptokinase were injected every five minutes. Every 15 minutes the catheter was advanced within the thrombus. In long stenoses 2,500–5,000 units of heparin were administered to avoid rethrombosis of the proximal segment. The recanalization was completed by angioplasty. Forty-seven patients with iliac or femoropopliteal obstructions of more than six weeks duration (up to one year, mean four months) and a length of 10–65 cm (mean 22 cm) were included in this study. The primary recanalization rate was 75%; the patency rate after two weeks was 68%. Failure of recanalization was most commonly caused by subintimal dissection. The procedure took 1–7 hours (mean 2.5 hours), and the total dose of streptokinase was 30,000–185,000 units (mean 70,000 units).

3:01 P.M.

993. Expandable Intraluminal Graft: A Preliminary Study

Julio C. Palmaz, M.D., San Antonio, TX, Randy R. Sibbitt, M.D., Stewart R. Reuter, M.D., J.D., Fermin O. Tio, M.D., William J. Rice, M.D.

In an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire with soldered cross points. The resulting tubular mesh has a wall thickness of 20–45 microns and a 98% open surface. Eleven grafts of six, eight, and 10 ml in diameter by 20 ml in length were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies up to 8.5 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. No long-term anticoagulation was used. Light and electron microscopy studies showed complete endothelization of the inner surface of the graft at three weeks.